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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,186	02/26/2004	Kenan C. Murphy	UMY-046	9606
959	7590	04/09/2007	EXAMINER	
LAHIVE & COCKFIELD, LLP ONE POST OFFICE SQUARE BOSTON, MA 02109-2127			SCHLAPKOHL, WALTER	
			ART UNIT	PAPER NUMBER
			1636	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/09/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/789,186	MURPHY, KENAN C. <i>mkf</i>	
	<b>Examiner</b>	<b>Art Unit</b>	1636
	Walter Schlapkohl		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 08 January 2007.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 15,21-26 and 44-47 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 15,21-26 and 44-47 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 26 February 2004 is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____                          |

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**DETAILED ACTION**

Receipt is acknowledged of the papers filed 1/8/2007 in which claims 1-14, 16-20 and 27-43 were cancelled; claims 15 and 21-26 were amended; and claims 44-47 were added. Claims 15, 21-26 and 44-47 are pending and under examination in the instant Office action.

Any rejection of record not recited herein is hereby WITHDRAWN.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15, 21 & 44-47, and therefore dependent claims 22-26, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These are new rejections which were, in part, necessitated by Applicant's amendment.

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Claim 15 recites "[a] recombinant organism comprising a PCR-mediated gene replacement vector comprising:

- (a) a  $\lambda$  *exo* and a  $\lambda$  *bet* nucleotide sequences encoding bacteriophage  $\lambda$  *Red* recombinase;
- (b) a  $\lambda$  *gam* nucleotide sequence encoding bacteriophage anti-RecBCD;
- (c) a *P<sub>Tac</sub>* promoter sequence operably linked to the nucleotide sequence of (a) and (b); and
- (d) a nucleotide sequence encoding LacI operably linked to its native promoter; and

(e) at least one origin of replication sequence which confers low copy number on the vector,  
wherein the recombinant organism is a pathogenic species" in lines 1-11 (emphasis added).

Claim 15 is vague and indefinite in that the metes and bounds of a "PCR-mediated gene replacement vector" are unclear. Does Applicant intend a vector which is capable of replacing genes with PCR products, such as a vector which encodes a recombinase; or does Applicant intend, e.g., a vector which has had a gene replaced as a result of a PCR reaction?

Similarly, claims 45-47 recite a "PCR-mediated gene replacement vector" in lines 1-2 of each claim. Claims 45-47 are also vague and indefinite as explained for claim 15, above.

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Claim 15 is also vague and indefinite in that the metes and bounds of an "origin of replication sequence which confers low copy number on the vector" are unclear. For example, is an origin of replication sequence which confers a "low" copy number on the vector one that results in an average of 5, 500 or 5,000 copies of the vector per transformed organism? The specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Similarly, claims 45-47 recite an "origin of replication sequence which confers low copy number on the vector" in lines 9-10 of each claim. Claims 45-47 are also vague and indefinite as explained for claim 15, above.

Claim 15 is also vague and indefinite in that the metes and bounds of a "pathogenic species" are unclear. Does Applicant intend any organism which can be opportunistically pathogenic to humans, such as pathogenic strains of bacteria; or does Applicant, intend, for example any organism which can be pathogenic to another organism?

Similarly, claim 21 recites a "pathogenic species" which is "pathogenic *Escherichia coli*" in lines 1-2. Claim 21 is vague and indefinite in that it is unclear which strains of *E. coli* are encompassed as "pathogenic" species. Does Applicant intend

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only species of *E. coli* which are opportunistically pathogenic to humans or does Applicant intend any *E. coli* species which is pathogenic to another organism?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15, 21-26 and 44-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection. This is a new rejection necessitated by Applicant's amendment.**

The specification as originally filed does not provide support for the invention as now claimed: "[a] recombinant organism comprising a PCR-mediated gene replacement vector..." (see claim 15 and 45-47, lines 1-2; emphasis added). The specification does not provide sufficient blazemarks nor direction for the instant vectors encompassed by the above-

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mentioned limitation, as currently recited. The instant claims now recite a limitation, which was not clearly disclosed in the specification as filed, and now changes the scope of the instant disclosure as filed. Such a limitation recited in the present claims, which did not appear in the specification as filed, introduces new concepts and violates the description requirement of the first paragraph of 35 U.S.C. 112.

### ***Conclusion***

No claim is allowed.

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant does submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance.

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Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent applications to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached at (571) 272-0739.

Walter A. Schlapkohl, Ph.D.  
Patent Examiner  
Art Unit 1636

March 19, 2007

DAVID GUZO  
PRIMARY EXAMINER

